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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,533	07/25/2003	Hiroshi Iseki	P23564	1145

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GREENBLUM & BERNSTEIN, P.L.C.  
1950 ROLAND CLARKE PLACE  
RESTON, VA 20191

EXAMINER

KOSOWSKI, ALEXANDER J

ART UNIT PAPER NUMBER

2125

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/626,533

Applicant(s)

ISEKI ET AL.

Examiner

Alexander J. Kosowski

Art Unit

2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/27/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

- 1) Claims 1-20 are presented for examination.

***Claim Objections***

- 2) Claims 1 and 2 are objected to because of the following informalities:

Referring to claim 1, line 4, the acronym "MRI" is not defined.

Referring to claim 1, line 7, the word "born" should read --bone--.

Referring to claim 2, line 4, the word "born" should read --bone--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

- 3) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 4) Claims 1, 3-11 and 13-20 are rejected under 35 U.S.C. 102(b) as being unpatentable by D'Urso (U.S. pat 6,112,109).

Referring to claim 1, D'Urso teaches a method comprising the steps of: obtaining a plurality of tomographic image data of a bone based on measurement data by MRI and producing three-dimensional image data of the bone based on the plurality of tomographic image data (col. 7 lines 20-31); and estimating a shape of a missing born that was previously present or should have been present in the defect of the bone to obtain three-dimensional data of the implant (col. 8 lines 55-61), wherein the three-dimensional data of the implant is modeled such

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that at least a part of the outer periphery of the implant is conformable with the shape of the side walls of the defect of the bone (col. 7 lines 58-63 and col. 8 lines 43-50).

Referring to claim 3, D'Urso teaches the method as claimed in claim 1, wherein the estimating step comprises the steps of: estimating a provisional shape of the implant which has a contour conformable with the shape of a contour of periphery of the side walls of the defect at the distal surface of the bone and has a predetermined thickness, and deleting data of portions of the provisional shape of the implant that overlap the bone from the data of the provisional shape of the implant so that the three-dimensional data of the implant has an outer peripheral shape that is conformable with the shape of the side walls of the defect (col. 8 lines 38-61).

Referring to claim 4, D'Urso teaches the method as claimed in claim 1, wherein the estimating step comprises the steps of: producing data of a contour of a distal surface of the implant so that the contour is conformable with the shape of a contour of periphery of the side walls at the distal surface of the bone, estimating a provisional shape of the implant which has a predetermined thickness and has a substantially predetermined shape in the thickness direction thereof using the data of the contour of the distal surface of the implant, and deleting data of portions of the provisional shape that overlap the bone from the data of the provisional shape of the implant so that the three-dimensional data of the implant has an outer peripheral shape that is conformable with the shape of the side walls of the defect (col. 8 lines 38-61).

Referring to claim 5, D'Urso teaches the method as claimed in claim 1, wherein the estimating step comprises the steps of: producing data of a contour of a distal surface of the implant so that the contour is conformable with the shape of a contour of periphery of the side walls at the distal surface of the bone, estimating a provisional shape of the implant which has a

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predetermined thickness and has a substantially predetermined shape in the thickness direction thereof using the data of the contour of the distal surface of the implant, and correcting the data of the provisional shape so that the three-dimensional data of the implant has an outer peripheral shape that is conformable with the shape of the side walls of the defect by comparing the estimated data of the provisional shape of the implant with the data of the side walls of the three-dimensional image data (col. 8 lines 38-61).

Referring to claim 6, D'Urso teaches the method as claimed in claim 1, wherein when the implant is applied to the defect of the bone, the distal surface of the implant forms a continuous surface with the distal surface of the bone (col. 9 lines 22-29 and col. 10 lines 18-22 and Figure 7).

Referring to claim 7, D'Urso teaches the method as claimed in claim 1, wherein the bone substantially has plane symmetry, in which the estimation of the shape of the missing bone is carried out utilizing data of a portion in the three-dimensional image data which is plane-symmetrical with the defect in the three-dimensional image data (col. 9 lines 1-20).

Referring to claim 8, D'Urso teaches the method as claimed in claim 1, wherein the bone is a cranium bone (col. 7 line 57).

Referring to claim 9, D'Urso teaches the method as claimed in claim 1, wherein the plurality of tomographic images for producing the three-dimensional image data are taken with a predetermined slice interval between the adjacent images, in which the slice interval is in the range of b 0.1 to 5 mm (col. 2 lines 21-30).

Referring to claim 10, D'Urso teaches an implant which is manufactured based on a model prepared in accordance with the modeling method above (col. 8 lines 62-64).

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Referring to claim 11, D'Urso teaches the implant as claimed in claim 10, wherein the implant is manufactured through a manufacturing process which comprises: a first step for forming a layer made of material powder; and a second step for hardening the material powder by making at least a part of the layer contact with a reaction liquid, wherein the first step and the second step are carried out repeatedly to obtain a laminate comprised of a plurality of the layers, thereby manufacturing an implant having a shape corresponding to the three-dimensional data of the implant provided by the modeling method (col. 4 lines 10-21 and col. 5 lines 4-10).

Referring to claims 13-20, see rejection of claim 10 above.

***Claim Rejections - 35 USC § 103***

5) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso, further in view of Barlow et al (U.S. pat 6,540,784)..

Referring to claim 12, D'Urso teaches the above. D'Urso also teaches that the implant may be porous (col. 6 lines 22-23). However, D'Urso does not explicitly teach that the implant has a porosity of 10 to 90 vol %.

Barlow teaches a method of creating an implant whereby the implants have a porosity 50-80% (col. 8 lines 29-39).

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Therefore, it would have been obvious to one skilled in the art at the time the invention was made to utilize a porosity of 10-90% in the invention taught by D'Urso since porosity is related to a rate of resorption (Barlow, col. 2 lines 45-59) and since having porous regions permits bonding by tissue migration (D'Urso, col. 6 lines 22-23).

7) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso, further in view of Toth et al (U.S. Pat 6,775,352).

Referring to claim 2, D'Urso teaches the above. However, D'Urso does not explicitly teach that the tomographic image data is obtained by obtaining threshold value inverting data by inverting a threshold value of the measurement data by MRI, and then extracting a bone region from the threshold value inverting data.

Toth teaches inverting a threshold value of a measurement for an MRI to extract a bone region (col. 5 lines 12-41).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to obtain a threshold value inverting data by inverting a threshold value of the measurement data by MRI, and then extracting a bone region from the threshold value inverting data in the method taught above since this would allow for projection profiles from the MRI scan to be generated (Toth, col. 5 lines 29-40).

### ***Conclusion***

8) The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Swaelens (U.S. Pat 5,768,134) – teaches constructing implants by lamination.

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Biscup (U.S. Pat 6,786,930) – teaches constructing molded surgical implants.

Leake (U.S. Pat 4,976,737) – teaches bone reconstruction.

Robertson (U.S. Pat 4,873,707) – teaches x-ray tomography.

White (U.S. pat 4,436,684) – teaches a method of forming prostheses.

Wood (U.S. pat 6,083,264) – teaches implant material for augmenting bone.

Friedman (U.S. pat 5,503,164) – teaches repairing bone defects.

Peckitt (U.S. Pat 6,254,639) – teaches prosthetic implants.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander J Kosowski whose telephone number is 571-272-3744.

The examiner can normally be reached on Monday through Friday, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. In addition, the examiner's RightFAX number is 571-273-3744.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

Alexander J. Kosowski  
Patent Examiner  
Art Unit 2125



**LEO PICARD**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 2100**